EXHIBIT 32

PACIFIC MEDICAL pacmed.com Equipment

TechNation
EMPOWERING THE BIOMEDICAL / CE PROFESSIONAL

ECRI Institute
The Discipline of Science. The Integrity of Independence.

ECRI Update: You're Getting Warm: Uncovering Forced-air Warming Units

Posted By: TechNation Development Team on: May 01, 2017 In: Breaking News, ECRI Updates, Industry Updates, Magazine

Forced-air warming units heat patients convectively (i.e., warm air is gently blown across the patient beneath the air blanket). These units were originally used in the postanesthesia care unit (PACU) for whole-body warming following surgical procedures; they have since moved into the operating room (OR) for warming parts of the body during surgery. In all cases, they are designed to reduce hypothermia and speed recovery time. In order to speed healing, shorten hospital stays, and reduce wound infections, maintaining normothermia in the perioperative setting is advised. Although these units are used mostly on surgical patients, they are also employed in the emergency department for rewarming hypothermic patients.

When the body loses too much heat and cannot maintain its normothermia of 36.6 to 37.5 degrees Celsius (97.9 to 99.5 degrees Fahrenheit), the body is in a state of hypothermia. Upon admission to the PACU, adult surgical patients can become hypothermic due to large heat losses sustained during surgery. Induced heat loss is the intentional lowering of the patient's body temperature by heat exchange through a heart/lung machine or by surface cooling; it is used before cardiopulmonary bypass surgery to help induce cardiac arrest and to reduce metabolic oxygen demand. Inadvertent heat loss that results in average temperature drops of 0.5 to 1.5 degrees Celsius (0.9 to 2.7 degrees Fahrenheit) occurs for a number of reasons.

The body attempts to regain heat lost in the OR by shivering during the postoperative period. Shivering, which can intensify to tremors or violent shaking, poses extreme danger to the postsurgical patient because of the high energy demand required to sustain the shaking. The adverse consequences of the metabolic stress imposed by this increased energy demand include the following:

- Interference with a patient's emergence from anesthesia
- Increased risk of ventricular fibrillation, stroke, postoperative deep-vein thrombosis, and pulmonary embolization
- Increased blood viscosity (red blood cell sludging)
- Decreased perfusion of vital organs
- Inhibition of hepatic and pancreatic activity, leading to changes in glucose metabolism
- Decreased renal blood flow, resulting in decreased glomerular filtration, loss of proteins, and subsequent increased risk of wound infection

Forced-air warming units are used to combat hypothermia and related deleterious effects. Other measures to prevent hypothermia include raising the OR temperature, keeping the patient covered with warmed blankets as long as possible before surgery, using heated humidifiers in the anesthetic breathing circuit, and using fluid warmers. Because most of these measures are too diffusive to be effective or may impede surgical procedures, they have not gained wide acceptance.

Principles of Operation

A forced-air warming unit consists of a thermostatically controlled heater, a fan (blower), a control panel, a disposable accessory (e.g., blanket, gown) and a flexible hose that attaches to the disposable accessory. A filter is mounted at the blower air intake, and dust and bacteria are removed from the incoming air.

The filtered air is warmed by a heater and directed into the flexible hose that connects the blower to the blanket. A remote sensor at the hose inlet monitors the temperature of the air being directed to the patient. When the temperature of the heated air reaches the set point (e.g., 44 degrees Celsius [111.2 degrees Fahrenheit]), a thermostat turns off the heater to prevent thermal injury to the patient.

Patient warming blankets are placed on top of the patient's bed or operating table and may be secured with clips. Some blankets may have an adhesive strip to affix the blanket to the patient and to prevent air from blowing into the operating field. Warming blankets used in the OR are designed to cover only the upper or lower body; a full blanket cannot be used because of the need to establish the operating field and to maintain sterility. Blankets for the PACU or emergency department are full-body blankets, with the hose inlet usually located by the patient's feet. These blankets generally offer access panels that allow a nurse to easily lift up a portion of the blanket to check the patient's dressings, infusion lines or skin tone.

Blankets come in various sizes, including pediatric, adult, lower body, upper body and full body. Specialized sizes designed for pre- and postoperative care are available from some manufacturers.

The blanket material, which is usually latex-free and nonflammable, is bonded into tubular channels. Warm air entering the blanket fills the channels, causing them to inflate and the blanket to flex concavely around the patient. Small slits or holes on the patient side of the blanket allow warm air to blow on the patient. The result is a layer of warm air between the patient and the blanket.

Forced-air warming units use convective heating in contrast to circulating-water warming units which use conductive heating (i.e., heat absorbed from hotter objects in contact with the skin). Whether convective or conductive heating is more effective is still a matter of debate; however, proponents believe forced-air blankets are easier to transport and store and are more comfortable for the patient than circulating-water blankets.

Reported Problems

Forced-air warming units, like other heating devices, have the potential to cause burn injuries. Patient burns with forced-air units usually result from improper placement of the blanket under the patient or from use of the device for extended durations on maximum temperature settings. One study identified the following operator errors, which have resulted in patient burns:

- Warming of nonperfused or poorly perfused skin
- Contact of heated plastic with skin when the unprotected side of the blanket is placed against the patient (labels indicating which side of the blanket should face the patient are intended to prevent this misapplication)
- Constant contact of the blower hose with the skin of the lower extremities
- Use of a unit without a dedicated blanket (i.e., a warming hose inserted under bed linen)
- Use of another manufacturer's blanket
- Use of a model intended for unanesthetized patients on anesthetized patients (models for unanesthetized patients have a higher heat output)

Use of the device for prolonged durations may not be safe under some circumstances, even when the device is used correctly. A general guideline to follow is that the maximum temperature setting should not be used on patients in the presence of the following conditions, which could increase the risk of thermal injury:

- Low cardiac output
- Peripheral vascular disease (occlusive or diabetic)
- Total immobilization
- Unconsciousness
- Poor peripheral perfusion
- Marginal cutaneous perfusion

Additionally, the maximum temperature setting should not be used on patients who require warming for an extended period of time, unless they are under constant supervision. The operator should frequently check patient temperature and vital signs during extended usage. In all cases, operators should reduce the temperature or end treatment when normothermia is achieved.

Users should also be aware of the potential for thermal damage to medical devices. Heat from a warming unit can increase the pliability of medical tubing. It is not uncommon for tracheal tubes to kink within the airway, where they are exposed to body temperature.

Air jets, which cause an uneven concentration of air, can interfere with the distributed warming forces and result in burns at localized hot spots. This can occur if blower air is not distributed evenly. Blanket ballooning is another potential complication that occurs if the blanket cover is made from a nonbreathable material.

There is increasing scrutiny of forced-air warming units and a possible link to infection as a result of airborne contamination. While studies have shown no proof of this, there is still a concern that the blanket can increase bacterial contamination to the surgical site.

Replacing air filters at recommended intervals may help prevent these problems.

ECRI Institute Recommendations

ECRI Institute recommends that forced-air patient warming units have audible and visual overtemperature alarms because they increase the likelihood that a caregiver will quickly respond to a device-related problem. The highest temperature setting should be limited to 46 degrees Celsius (114.8 degrees Fahrenheit); higher temperatures increase the risk of thermal skin injury. As an additional safety feature, an internal thermostat should turn off the heater circuit if the temperature reaches 53 degrees Celsius (127.4 degrees Fahrenheit).

Warming units should have single-use disposable blankets (with labels indicating which side of the blanket should face the patient); single-use blankets help minimize cross-contamination during surgery. The unit and/or the heater should automatically shut off if a fault causes the air temperature to exceed the unit's setting. Dual safety thermostats provide extra overtemperature protection. A warming unit should have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds.

This article is adapted from ECRI Institute's Healthcare Product Comparison System (HPCS), a searchable database of technology overviews and product specifications for capital medical equipment. The source article is available online to members of ECRI Institute's HPCS; learn more at www.ecri.org/components/HPCS.